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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/653,325	09/02/2003	Allan H. Graff	C75128-1	2971

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	PAPER NUMBER
1618	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/653,325	GRAFF ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 17-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 17-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks, filed 12/11/06. Claim 16 is canceled. Claims 1-15 and 17-32 are pending.

Previous rejections that are not reiterated herein are withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 2, 3, 6, 7 and 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 2 and 3 recite the limitation "said active agent" in line 1. There is insufficient antecedent basis for this limitation in claim 1. The claim 1 is amended to recite "nicotine active" in place of active agent so that the nicotine active does not provide antecedence for active agent in claims 2 and 3.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-11, 13-15, 22, 26, 27 and 32 remain rejected under 35 U.S.C. 102(b) as being anticipated by Muhammad et al. (US 5,167,964).

Muhammad discloses flavored lozenges formulation and that lozenge bases are generally hard boiled candy lozenges or compressed tablet lozenges (column 8, lines 53-58). The disclosure of lozenges meets the limitation of claim 27. Muhammad specifically discloses that hard-boiled candy lozenges are amorphous or glassy (column 8, lines 59-64) meeting the limitation of claim 1a. Muhammad's formulation comprises medicaments and nicotine is specifically mentioned (column 4, lines 47 and 48) with the nicotine meeting the limitation of claims 1c and claims 2, 3, 16 and 32. The formulation comprises bulking agents, flavoring agents sweetening agents and buffers (column 8, lines 31-33; column 2, lines 60-65; column 10, lines 64-68); the buffering agents and flavoring agents meet the limitations of claims 22 and 26 and with regards to claim 26, "non-pharmacological component" is a flavor agent according to the instant specification at paragraph [0039]. The formulation may comprise 95% of a mixture sugar alcohols of sorbitol and mannitol in a ratio from about 9.5:0.5 to about 7.5:2.5 (column 9, lines 12-17) meeting the limitations of the claim 1b and the 95% sugar alcohol of Muhammad meets the limitations of claims 13-15. Claims 6-8 recite the properties of the dosage form of claim 1, and since a composition cannot be separated from its properties and because Muhammad discloses the dosage of claim 1, it flows that the dosage form of Muhammad possesses the properties recited in claims 6-8. Sufficient amount is any amount deemed sufficient by the artisan. For example, Muhammad specifically discloses that the effective amount of the medicament may vary depending on the recommended therapeutic dosage or the

dose permitted for the particular medicament and that such dosages are known to the skilled artisan in the medical arts (column 5, lines 10-16). Furthermore, the formulation/dosage of Muhammad contains suspending or thickening agents such as carrageenans, xanthan gums, gelatin and celluloses, with the preferred amount of the thickener present at from about 1% to about 15% and a point within this range anticipates the recited amounts of gum in claims 9-11 and the presence of xanthan gum in the dosage of Muhammad meets the limitations of claims 4, 5 and 9-11. The nicotine is contained in the glassy matrix.

Response to Arguments

6. Applicant's arguments filed 12/11/06 have been fully considered but they are not persuasive.

Applicant argues that a) the semi-enteric drug delivery system of Muhammad does not contain water-soluble gelling gum and that when a gelling gum is disclosed, the gelling gum is in the suspension and not in the hard confectionary dosage form; b) the dosage form of Muhammad cannot be said to teach or suggest that the hard confections be modified to include water soluble gelling gums, and "particularly at the levels taught in the present invention," which is an amount that provides oral dissolution of the glassy matrix to release desired amount nicotine and that column 2, lines 28-32 of Muhammad describes drug release in the stomach and intestines.

Response:

Regarding a), while Muhammad discloses suspending or thickening agents in amounts of up to 20% and preferably in amounts of from about 1% to about 15% relative to the weight of the suspension in column 11, lines 1-6, it is noted that the suspension are semi-enteric as stated in column 10, lines 51-57); and further review of Muhammad shows that Muhammad discloses

that the semi-enteric drug delivery systems can be admixed into hard and soft confections (column 12, lines 53-61) and the suspensions as indicated in column 10, lines 51-57 are semi-enteric. Therefore, the hard confection contains xanthan gum or gelatin or microcrystalline cellulose, the xanthan gum meeting water-soluble gum as in claims 4, 5.

Regarding b), the water-soluble gum is present at 0.5% to 5% in instant claims 9-11. Muhammad discloses water-soluble gum in preferred amounts of from about 1% to about 15% and a point within the disclosed range touches at least a point in the range of 0.5% to 5%. Thus, no modification is required with respect to the water-soluble gum and the amount of the water-soluble gum. Claim 1 is a hard-boiled dosage form and the recitation of "orally dissolving" is in the preamble and is a characteristic of the dosage form and similar dosage form will under go the same dissolution when ingested.

The rejection is maintained.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhammad et al. (US 5,167,964).

Muhammad is discussed above. While Muhammad discloses the use of phosphate buffers (column 2, line 65 and column 10, lines 64-66), there is no disclosure for specific phosphate buffers. But, the buffers recited in claim 23 and the buffers of claim 24 are common phosphate and carbonate buffers that can be used interchangeably to maintain the pH of the product at the desired pH level. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the known phosphate and carbonate buffers and expect the formulation to be buffered at the desired pH.

10. Claims 12, 19-21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhammad (US 5,167,964) in view of Rapp et al. (US 6,180,143 B1) or Burnick et al. (US 2003/0017202 A1).

Muhammad discloses the dosage of claim 1. Muhammad does not disclose the mixed sugar alcohols of claims 12 and 21. Regarding claim 25, it is noted that the dosage formulation of Muhammad comprises the sugar alcohol recited in claim 25 and the ordinary skilled artisan would know to use amounts of the sugar alcohols desired in the production of the lozenges.

However, Rapp discloses nicotine formulation that contains a sweetening agent mixture of 1.6-GPS, 1.1-GPS and 1.1-GPM (abstract; column 4, lines 38-67; claim 9), the sweetener mixture is comprised of 10-50% by weight of 1,6-GPS, 20% by weight of 1,1-GPS and 30-70% by weight of 1,1-GPM (column 2, lines 46-60; column 4, line 43-67; claims 2-5 and 14). The sweetener in Rapp and in the amounts disclosed renders obvious the sweetener of claims 12, 19 and 20. Example 3 uses ISOMALT, a sweetener that is a mixture of 1,6-GPS and 1,1-GPM; the ISOMALT is the sugar alcohol present in claim 21. Also, Burnick discloses formulation that contains nicotine, ISOMALT and xanthan gum (abstract; paragraph [0012]; paragraph [0015].

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the nicotine lozenge Muhammad. One having ordinary skill in the art would have been motivated to use mixed sugar alcohols known in the art to be formulated with nicotine according to Rapp or Burnick with the expectation of imparting low hygroscopy to the lozenge. ISOMALT is a mixture of 1,6-GPS and 1,1-GPM.

Response to Arguments

11. Applicant's arguments filed 12/11/06 have been fully considered but they are not persuasive.

Applicant argues that Muhammad does not disclose glassy matrix or base that contains at least one substantially non-hygroscopic sugar alcohol that is capable of forming a glassy structure, does not disclose glassy matrix or base that contains water soluble gelling gum present in amounts that would provide an oral dissolution rate of the glassy matrix so as to deliver desired amount of nicotine via the oral mucosa prior to ingestion into the stomach; that there is no motivation to modify Muhammad to ensure that the desired

amount of nicotine active is delivered via oral mucosa; that neither Rapp nor Burnick discloses an oral dosage form comprising a glassy matrix so that combination of Rapp or Burnick with Muhammad would not result in the claimed composition.

Response:

Muhammad discloses hard-boiled candy lozenges that are amorphous or glassy (column 8, lines 59-64), the semi enteric delivery system of Muhammad in the form of suspension may be admixed into hard or soft confection according to column 12, lines 53-56; column 11, lines 1-6. Thus as discussed above the matrix dosage form of Muhammad contains water-soluble gelling gum. Same compositions would behave alike when placed in an environment since the properties/characteristics of composition/product/dosage cannot separated from the composition so that same compositions would exhibit the same characteristics when placed in same/similar environment.

Rapp and Burnick are relied upon for disclosing nicotine compositions that contain ISOMALT, a mixture of 1,6-GPS and 1,1-GPM sugar alcohols. Burnick discloses an oral dosage form (see abstract) and Rapp discloses a chewing gum formulation, which is an oral form. Applicant appears to attack the individual references to show that the claimed invention is non-obvious while the combined references render the claimed invention in claims 12, 21 and 25 and all the limitations in claims 12, 21 and 25.

12. Claims 17, 18 and 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muhammad et al. (US 5,167,964) in view of Santus (US 6,280,761)

Muhammad is described above for disclosing nicotine dosage form in a glassy matrix. Types of nicotine are known in the art as evidenced by the disclosure of Santus that nicotine

polacriflex, a nicotine gum is a commercially available source of nicotine for replacement therapy (column 2, lines 8-11), meeting claim 17. Muhammad does not disclose a method of reducing nicotine craving. Santus describes a method for smoking cessation therapy, the method, comprising administering nicotine lozenge to a person in need thereof to satisfy transient craving (abstract; column 4, lines 19-28) and further discloses that lozenges containing fairly low doses of nicotine in preferred amounts of 0.5 to 5 mg, and in most preferred amounts of 0.5 to 2 mg are administered (column 6, lines 3-9), thus meeting claims 18, 27, 28 and 31. Administration of the dosage form of Muhammad as modified with Santus would inherently produce blood plasma nicotine levels of claims 29 and 30. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use modified dosage form of Muhammad in which between 0.5 and 5 mg nicotine is used according to Santus with the expectation that the low dose of the nicotine in the lozenges would satisfy transient craving, which would lead to smoking cessation according to Santus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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